



DEPARTMENT OF DEFENSE

Office of the Secretary

Extension of the Comprehensive Autism Care Demonstration for TRICARE Eligible Beneficiaries Diagnosed With Autism Spectrum Disorder

AGENCY: Department of Defense.

ACTION: Notice of an extension of the Comprehensive Autism Care Demonstration (ACD) for all Applied Behavior Analysis (ABA) services for all TRICARE eligible beneficiaries diagnosed with Autism Spectrum Disorder (ASD).

SUMMARY: This notice provides a five-year extension to the Military Health System's (MHS) demonstration project entitled Comprehensive ACD (the "Demonstration"), which is authorized to render clinically necessary and appropriate ABA services for the core symptoms of ASD. The purpose of the Demonstration is to analyze and evaluate the appropriateness of the ABA services tiered delivery model under TRICARE (the medical benefit) in light of current and anticipated practice guidelines. In addition to a pending independent research study and a Congressionally-required independent National Academies of Sciences, Engineering, and Medicine analysis, based on the agency's experience in administering ABA services under the Demonstration (including engagements with beneficiaries, providers, advocates, associations, and other payers), more data collection and analysis is required to determine the appropriate structure of implementing ABA services as either a medical treatment or other modality, under the TRICARE program coverage requirements.

DATES: The Demonstration will continue through December 31, 2028.

ADDRESSES: Defense Health Agency, Health Plan Operations, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042.

FOR FURTHER INFORMATION CONTACT: For questions pertaining to this demonstration project, please contact Ms. Valerie Palmer at (303) 676-3557.

SUPPLEMENTARY INFORMATION: On June 16, 2014, Department of Defense published a Notice in the Federal Register (FR) (79 FR 34291), as amended by 80 FR 30664 (May 29, 2015), of a TRICARE demonstration to further analyze and evaluate the appropriateness of the ABA tiered delivery model under TRICARE. The purpose of the Demonstration was to determine the appropriate provider qualifications for the proper diagnosis of ASD and for the provision of ABA services, assess the feasibility and advisability of establishing a beneficiary cost share for ABA services for the treatment of ASD, and develop more efficient and appropriate means of increasing access to and delivery of ABA services under TRICARE while creating a viable economic model and maintaining administrative simplicity. The Demonstration was implemented on July 25, 2014, with the original authority set to expire on December 31, 2018; however, an extension of the authority for the Demonstration until December 31, 2023, was granted, as documented via a FR notice published on December 11, 2017 (82 FR 58186). The notice stated that additional analysis and experience were required to determine the appropriate characterization of ABA services as a medical treatment, or other modality, under the TRICARE program coverage requirements. While much has been learned about ABA services administration under the TRICARE program, additional data are required to support a final determination regarding the appropriate provider qualifications for the proper diagnosis of ASD and for the provision of ABA services, the individual characteristics for patient/beneficiary improvement, and the appropriate clinical ABA services under the TRICARE benefit.

ABA services are currently provided through the Demonstration and managed by existing TRICARE regional Managed Care Support Contractors (MCSCs). Under the Demonstration, the Department implemented a provider model that allows reimbursement for ABA services rendered by providers who are not otherwise eligible for reimbursement. Approximately 16,000 beneficiaries diagnosed with ASD participate in the program annually with Demonstration enrollment continually fluctuating with new and terminating participants. Unlike the TRICARE Basic medical benefit, many TRICARE standards had to be modified and exceptions to policy

made due to the unique and evolving nature of ABA service provision or Congressional direction, such as: diagnosis and referral procedures; ABA provider qualifications and credentialing/certification; utilization management reviews; and reimbursement rate methodology. Since implementation of the Demonstration, Congress directed the agency to add outcome measures as a requirement to the program. Outcome measures were implemented on January 1, 2017, and are aimed at assessing individual progress for each beneficiary, as well as evaluating program effectiveness with the beneficiary population participating in the Demonstration. Preliminary outcome findings for one of three outcome measures were first reported in Quarter 1, Fiscal Year (FY) 2019. Subsequent quarterly and annual reports continued to highlight findings based on only one outcome measure. Inconsistencies in data collection methods and reporting from participating providers limited the Department's ability to analyze the other two outcome measures.

In addition to the Demonstration's outcome measures, a grant was awarded under the Congressionally Directed Medical Research Program (CDMRP) to the University of Rochester in September 2018 that is evaluating traditional intensive ABA services compared to a modified ABA service delivery model (<https://clinicaltrials.gov/ct2/show/study/NCT04078061>). Early intensive behavioral intervention (EIBI) for toddlers and preschoolers diagnosed with ASD typically involves 20 or more hours per week of individualized instruction based on ABA principles. Although research to date does not yet meet TRICARE's hierarchy of reliable evidence standards for proven medical care, research suggests that EIBI accelerates development of cognitive and adaptive skills in many children diagnosed with ASD. However, the evidence base has significant gaps, notably a shortage of randomized controlled trials (RCTs), limited data on whether EIBI reduces ASD symptoms, and few studies on outcomes of EIBI in community settings such as private agencies where most children with ASD receive services. Recently, research suggests that less intensive, time limited ABA interventions can effectively target specific core and associated features of ASD. The investigators in the CDMRP study are

evaluating if combining targeted interventions via an individualized, adaptive, and modular ABA (MABA) approach (10 hours per week) could be at least as effective as EIBI (20 hours per week) over the course of a 24-week RCT at follow-ups conducted 24 weeks after intervention and 90 weeks after intervention.

It is anticipated that the results of the CDMRP study will not only further the Department's understanding of the impact of ABA services delivered to the Demonstration participants, but also that findings from this study may benefit the larger community of individuals diagnosed with ASD and their families. The findings will leverage clinical outcomes while informing program development, structure, and long term impacts. Additionally, the findings may offer more clinical program choices to families, potentially identifying variables beneficial to clinical success. Findings may also lead to lowering costs to families and payers while also increasing access to effective and targeted ABA services. This study is scheduled to conclude at the end of 2023.

Further impacting the Demonstration, Congress directed that, via enactment of the National Defense Authorization Act for FY 2022, Department of Defense enter into an agreement with the National Academies of Sciences, Engineering, and Medicine ("National Academies") to conduct an analysis on the effectiveness of the ACD and develop recommendations for the Department based on such analysis. The analysis would include, among other goals, a review of the expected health outcomes for an individual who has received ABA services over time, and other analyses to measure the effectiveness of the Demonstration. At the conclusion of the study, the National Academies will develop and provide the Department a list of findings and recommendations related to the measurement, effectiveness, and increased understanding of the Demonstration and its effect on beneficiaries under the TRICARE program. The National Academies study will take significant time to complete, and the Department will then require additional time to evaluate the National Academies' recommendations and make any appropriate and authorized changes.

Experience from administering the Demonstration to date informed the Department's ability to publish a significant policy update (March 23, 2021) to address the clinical needs of the beneficiary population as well as revise program oversight requirements. This policy update focused on providing enhanced beneficiary and family support; improving clinical outcomes; encouraging parental involvement; and improving utilization management controls. These revisions are anticipated to improve the quality of, and access to, clinically necessary and appropriate care and services, and will also improve management and accountability of both the MCSCs and ABA providers.

Based on the above factors, at this time, making any determination regarding the efficacy of ABA services as a medical benefit, or other coverage options, under TRICARE is premature, and it is necessary for the Department to extend the Demonstration beyond its expiration on December 31, 2023. While much information has been learned about ABA while administering services under the Demonstration authority, the Department needs time to further evaluate the goals of the Demonstration, collect and evaluate outcome measures, incorporate the results of the CDMRP study award, and address recommendations from the National Academies. In addition, by extending the Demonstration, the Department will not only be able to fully implement the program improvements, but also will continue to gain greater insight and understanding of the effectiveness of ABA services being delivered to TRICARE beneficiaries based on outcome data.

As the Department is pending a benefit determination, this extension will determine whether the Demonstration meets its stated purpose and will provide the Department with consistent and reliable information necessary to make a formal decision regarding the provision of the ABA services benefit. The Demonstration continues to be authorized by Title 10, United States Code, Section 1092.

Dated: July 29, 2022.

Aaron T. Siegel,
Alternate OSD Federal Register Liaison Officer,
Department of Defense.

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